USSN: 09/974,882 <u>Patent Application</u>

<u>REMARKS</u>

Claims 21 and 24-34 are pending. Applicants have not amended the claims or specification in this response. That said, they reserve the right to do so in this or a related application. Applicants respectfully request reconsideration of their claimed invention. They also ask that the Office make note of the attorney docket number now applied to this application, *i.e.*, GTI-1320-CT.

Priority and Rejection Under 35 U.S.C. § 102

Applicants wish to thank the Examiner for his thorough consideration of this application's priority. Attached hereto as Exhibit A, Applicants append the two-page transmittal paper that accompanied this application when it was filed on 10 October 2001, along with a copy of the acknowledgement postcard that accompanied the papers then filed. Applicants kindly direct the Examiner's attention to (i) the top one-third of page 1 of the transmittal letter, which in part provides, "Presented for filing a new CONTINUATION patent application of:"; and (ii) the bottom one-half of page 2 of the transmittal letter, which (a) twice reiterates that this application is a continuation of U.S. patent application serial no. 09/453,610, (b) references (albeit mistakenly) the '610 application's priority to provisional patent application serial no. 60/110,950, and (c) expressly incorporates by reference the two priority applications.

It is also important to appreciate that the first paragraph of the '610 application (paragraph 0001) correctly noted the provisional patent application serial number (*i.e.*, 60/110,951) to which this application ultimately claims priority.

In view of this information, Applicants respectfully submit that the application and its filing papers indeed set forth the proper priority claim and incorporate by reference each of the priority applications. As such, WO 00/34436 cannot constitute prior art to any of the pending claims, and thus Applicants request withdrawal of the 35 U.S.C. § 102(b) rejection.

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"Written Description" Rejection Under 35 U.S.C. § 112

Each of the pending claims also stands finally rejected as allegedly failing to comply with the written description requirement of 35 USC § 112, 2nd paragraph. Applicants respectfully traverse because the ordinarily skilled artisan would understand from the specification that the claimed methods can be used to introduce chromosomes into any human or animal cell. The suggestion in the Final Action that the skilled artisan would not appreciate this is simply untenable.

To begin with, and as acknowledged in the Final Action, paragraph 0005 of the specification expressly states that FACS methods are known to be useful for sorting "human and animal" cells. Paragraph 0025 also provides, "Cells contemplated as recipients or "hosts" for the chromosomal DNA include fibroblasts, parenchyma stem cells both hematopoietic and parenchymal or essentially any cell that can be exploited ex vivo for the purposes of gene delivery, and the like." No reasonable reading of the specification could lead to the conclusion that the methods described and claimed in the application do not concern human and animal cells, *i.e.*, cells to which gene therapy may be applied.

The application goes on to further teach that the methods described in the specification are useful in the context of gene therapy, *i.e.*, they can be used to introduce at least one additional chromosome into a cell outside of a patient's body. Indeed, the concept of gene transfer and the like, and devices for accomplishing the same, is mentioned throughout the specification (*see*, *e.g.*, the abstract and specification paragraphs 0002, 0003, 0008, 0009, 0011, 0012, 0025, 0030, 0031, 0035, 0036, 0037, 0038, 0039, 0040, and 0041). Thus, when the application is read in the proper context, it is clear that specification expressly supports the full scope of the invention as claimed.

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CONCLUSION

Applicants respectfully submit that all of the pending claims are in condition for allowance, and they earnestly solicit a notice to such effect. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.350.9690 so that they may be promptly resolved.

Dated: 4 July 2005

Respectfully submitted,

Daniel M. Chambers Attorney for Applicants BioTechnology Law Group

Reg. No. 34,561

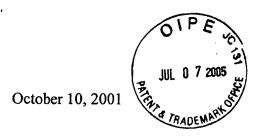
Attachment – Exhibit A (4 pages total)

USSN: 09/974,882



EXHIBIT A

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4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133 www.graycary.com O] 858-677-1456 F] 858-677-1465

Attorney Docket No.: GENE1320-2

Parent Application No. 09/453,610 Parent Filing Date: December 3, 1999

BOX PATENT APPLICATION

Commissioner for Patents Washington, D.C. 20231

Presented for filing is a new CONTINUATION patent application of:

Applicants:

Edward M. Nolan, Dietmar P. Rabussay and Gunter A. Hofmann

Title:

FACS ASSISTED METHODS FOR INTRODUCING INDIVIDUAL

CHROMOSOMES INTO CELLS (as amended)

The prior application is assigned of record to GENETRONICS, INC., by virtue of an assignment submitted to the Patent and Trademark Office for recording on February 23, 2000, at Reel 010564, Frame 0495.

Enclosed are the following papers, including all those required to receive a filing date under 37 CFR § 1.53(b):

	<u>Pages</u>
Specification	14
Claims	4
Abstract	1
Copy of executed	
Declaration from parent	3
Drawings - informal	3

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"EXPRESS MAIL" LABEL NUMBER EL617035901US

DATE OF DEPOSIT: October 10, 2001

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER OF PATENTS, BOX PATENT APPLICATION, WASHINGTON, D.C. 20231

TYPED ON PRINTED NAME

GNATURE OF PERSON MAILING PAPER OR FEE)

<u>LISA A. HAILE</u>

· Attorney Docket No.: GENE1320-2

Parent Application No. 09/453,610 Parent Filing Date: December 3, 1999

BOX PATENT APPLICATION

October 10, 2001 Page Two

Enclosures:

- A Copy of the Petition for Three (3) Month Extension of Time for parent application (U.S. Application Serial No. 09/453,610, filed December 3, 1999) (2 pages);
- Preliminary Amendment attached with Exhibit A (6 pages);
- Information Disclosure Statement and Copy of Form PTO 1449 (filed in the parent application) (3 pages);
- Information Disclosure Statement from International Search Report, copy of Form PTO 1449, and copy of International Search Report (filed in the parent application) (12 pages); (9pgs.)
- Copy of executed Power of Attorney By Assignee (2 pages);
- Copy of USPTO Notice of Recordation of Assignment, Copy of executed Recordation Form Cover Sheet and Assignment and By Inventors (7 pages);
- Check No. 491250 in the amount of \$370.00; and
- Return Receipt Postcard.

This application is a **CONTINUATION** and claims the benefit of priority under 35 USC § 120 of U.S. Application Serial No. 09/453,610, filed December 3, 1999, now pending, which claims priority under 35 U.S.C. § 119(e) of Provisional Application Serial No. 60/110,950, filed December 4, 1998. The disclosure of the prior application is considered part of and is incorporated by reference in the disclosure of this application.

Preliminarily, on page 1 of the specification, before line 1, insert:

--This application is a continuation and claims the benefit of priority under 35 U.S.C. § 120 of U.S. Application Serial No. 09/453,610, filed December 3, 1999, now pending, which claims priority under 35 U.S.C. § 119(e) of Provisional Application Serial No. 60/110,950, filed December 4, 1998, each of which is incorporated by reference in the disclosure of this application.--



EXPRESS MAIL LABEL NO.: EL617035901US

PATENT ATTORNEY DOCKET NO.: GENE1320-2

The Patent and Trademark Office date stamp sets forth the receipt date of:

Applicant or Patentee: Nolan, et al. Application Serial No.: Unassigned

Parent Application No.: 09/453,610 Parent Filing Date: December 3, 1999

FACS ASSISTED METHODS FOR INTRODUCING INDIVIDUAL

CHROMOSOMES INTO CELLS (as amended)

[X] Transmittal Letter [2 pgs-in duplicate] New CIP <u>CONT</u> DIV CPA (underl one) [X] Appln: [14] pgs of SPEC [4] pgs of CLAIMS [3] CLAIMS [1] pg of ABSTRACT

[X] Appln Cover Sheet (1 pg.)

[X] Drawings: [3] Sheets (Informal/Formal) [X] Check: \$370.00 (Check # 491250)

[X] Copy of executed Declaration from parent application

[X] Copy of the Petition for Three (3) Months Extension of Time for the parent application (U.S. Application Serial No. 09/453,610, filed 12/3/99)(2 pgs.)

[X] Preliminary Amendment - w/ Ex. A (6 pages)

[X] Copy of the Information Disclosure Statement & copy of Form PTO-1449 (filed in parent application) [3 pgs.]

[X] Copy of the Information Disclosure Statement from ISR, copy of Form PTO-1449, and copy of ISR (report) (filed in parent appl.) [12 pgs.] (9pgs.)

[X] Copy of executed Power of Attorney By Assignee [2 pgs.]

[X] Copy of USPTO Notice of Recordation of Assignment, copy of executed Assignment/Recordal Cover Sheet and Assignment and By Inventors [7 pgs.]

[X] Other: Return Receipt Postcard Date Filed: 10/10/01

Atty/Sec Initials: LAH/JML:ct Client/Matter No.: 104648-160132 Date=Date: 10/11/01

EL617035901US



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